

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Oral Suspension for Puppies Febantel 15 mg/ml / Pyrantel 5 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substances:

15 mg	Febantel
5 mg	Pyrantel (as pyrantel embonate 14.4mg)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Sodium benzoate (E211)	2.05 mg
Sodium propionate (E281)	2.05 mg
Ponceau 4R (E124)	0.25 mg
Sodium dihydrogen phosphate dihydrate	
Sorbitan oleate (E494)	
Povidone K25 (E1202)	
Polysorbate 80 (E433)	
Docusate sodium	
Bentonite (E558)	
Citric acid anhydrous (E330)	
Xanthan gum (E415)	
Propylene glycol (E1520)	
Purified water	

Pale red suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs (puppies and young dogs up to one year of age)

3.2 Indications for use for each target species

For the treatment of roundworm infections in puppies and young dogs up to one year of age caused by:

Ascarids:	<i>Toxocara canis</i> <i>Toxascaris</i> <i>leonina</i>
Hookworms:	<i>Ancylostoma caninum</i> <i>Uncinaria stenocephala</i>
Whipworm:	<i>Trichuris vulpis</i>

3.3 Contraindications

Do not use simultaneously with compounds containing piperazine as piperazine may block the action of pyrantel embonate contained in the product. Other worming products may contain piperazine.

Do not use simultaneously with other worming products without veterinary advice.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use during pregnancy

Do not use in lactating bitches

3.4 Special warnings

Care should be taken to administer the product according to the package leaflet and avoid unnecessary use of worming treatments, as this may increase the risk of development of resistance and could ultimately result in ineffective therapy. Advice from a veterinary or suitably qualified professional should be sought to identify the presence or risk of worm infection based on the animal's individual lifestyle.

Dogs may become re-infected with roundworms following treatment. Ongoing exposure to worms can occur from eggs in the environment, or by eating birds, small rodents or rabbits, or scavenging livestock carcasses. The need for and interval between treatments will vary depending on the dogs environment and lifestyle. For guidance specific to your dog, consult your vet or suitably qualified professional. Treating your dog will reduce the risk of other animals and humans being exposed.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The safety of the product has not been assessed in puppies younger than 2 weeks and weighing less than 0.6 kg.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Wash hands after use,

The product may cause skin or eye irritation.

Avoid direct contact with the skin and eyes. In case of accidental spillage wash the affected area immediately with clean running water.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorder ¹ (diarrhoea ¹ , vomiting ¹)
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¹ Mild and transient.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Do not use during pregnancy
Do not use in lactating bitches.

3.8 Interaction with other medicinal products and other forms of interaction

The anthelmintic effects of both pyrantel (spastic paralysis) and piperazine (neuromuscular paralysis) may be antagonised when the two drugs are used together. Other worming products may contain piperazine. Do not use simultaneously with other deworming products without veterinary advice

3.9 Administration routes and dosage

For oral use

Dosage and Treatment Schedule
Give 1 ml/kg of bodyweight

This equates to 15 mg/kg bodyweight febantel and 5 mg/kg bodyweight of pyrantel (as embonate) corresponding to 14.4 mg/kg pyrantel embonate.

Underdosing could result in ineffective use and may favour resistance development

To ensure administration of the correct dose, body weight should be determined as accurately as possible.

Ascarid roundworm infestation may occur in dogs at a very young age due to infection whilst within the womb, or via the mother's milk. For some animals, especially in case of severe infections, elimination of ascarids may be incomplete, and a potential risk of infections to humans cannot be excluded. Where epidemiologically appropriate, it is recommended that treatment should be started at 2 weeks of age and should be performed repeatedly at suitable intervals (for example every 2 weeks), until weaning. Otherwise treatment should be based upon confirmed infection, for example the results of faecal examinations.

The need for and frequency of re-treatment(s) should be based on professional advice (from a veterinarian or suitably qualified professional) and should take into account the local epidemiological situation and the animal's lifestyle.

Method of Administration

Single Oral administration.

The product may be given directly to the animal or mixed with feed using the syringe supplied with the pack. No special dietary measures are necessary; access to normal diet does not need to be limited before or after treatment.

1. Measure the animal's bodyweight accurately to ensure correct dosage.
2. Mix the product by gently turning the container upside down and then back upright a few times.
3. Remove the bottle cap and place the tip of the syringe provided into the neck of the bottle. Turn the bottle upside down and then pull the syringe plunger out allowing the liquid to flow into the syringe chamber. Continue pulling the plunger out until the liquid reaches the desired dosage line (1ml suspension per kilogram of bodyweight).
4. Turn the bottle upright and carefully separate the syringe from the bottle.
5. Replace the bottle top.
6. The measured amount of product may then be given to the animal. To do this, push the plunger to empty the full contents of the syringe directly into the corner of the mouth of the animal, or mix with food and ensure the full dose is ingested.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Doses of up to 5 times the therapeutic level of the product have been administered to puppies and young dogs without clinical signs of intolerance arising.

At 10 times the recommended dose the first sign of intolerance – vomiting – was evident.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AF02.

Fixed combination of two anthelmintics: a tetrahydro-pyrimidine derivative, pyrantel (as the embonate) and a pro-benzimidazole, febantel.

4.2 Pharmacodynamics

In this fixed combination product, the pyrantel and febantel act synergistically against nematodes (ascarids, hookworms and whipworms) of dogs. In particular, the spectrum of activity covers *Toxocara canis*, *Ancylostoma caninum* and *Trichuris vulpis*. Published data are also available to confirm that *Toxascaris leonina* and *Uncinaria stenocephala* are also susceptible to this particular combination of actives.

Febantel, N-{2-[2,3-bis,(methoxycarbonyl)-guanidino]-5-(phenylthio) phenyl}-2-methoxyacetamide, is a pro-benzimidazole. Within the mammalian system febantel undergoes ring closure forming fenbendazole and oxfendazole. It is these chemical entities which exert the anthelmintic effect by inhibition of tubulin polymerization. Formation of microtubules is thereby prevented, resulting in disruption to structures vital to the normal functioning of the helminth. Glucose uptake, in particular, is affected, leading to depletion in cell ATP. The parasite dies upon exhaustion of its energy reserves, which occurs 2-3 days later.

Pyrantel, (E)-1,4,5,6-Tetrahydro-1-methyl-2-[2-(2-thienyl) vinyl] pyrimidine pamoate belongs to the tetrahydropyrimidine type. Its mode of action is to stimulate nicotinic cholinergic receptors inducing spastic paralysis and thereby allowing removal from the gastro-intestinal (GI) system by paralysis.

4.3 Pharmacokinetics

Literature reports indicate after oral application of the recommended dose of 1 ml/kg bodyweight (corresponding to 14.4mg/kg pyrantel embonate and 15 mg/kg febantel) maximum serum concentrations for febantel were found between 1 and 6 hours with a C_{max} of 0.019 mg/l two hours after dosing. As febantel as a pro-drug is metabolised to fenbendazole which is further converted to oxfendazole, also these metabolites were measured. C_{max} of fenbendazole was 0.130 mg/l after 3 hours and C_{max} of oxfendazole was 0.157 mg/l at about 5 hours after application. The C_{max} of pyrantel (measured as pyrantel base) was 0.084 mg/l 2.5 hours after application.

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

Not applicable.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years

Shelf-life after first opening the immediate packaging: 12 weeks

5.3 Special precautions for storage

This unopened veterinary medicinal product does not require any special storage conditions.

After opening, store the product at a temperature not exceeding 25 °C.

5.4 Nature and composition of immediate packaging

White high density polyethylene bottle with polypropylene screw cap and low density polyethylene adapter insert.

Measuring device: Polyethylene syringe

Pack sizes: Bottles of 50 ml and 100 ml

Not all pack sizes may be marketed

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 08007/5002

8. DATE OF FIRST AUTHORISATION

17 April 1998

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

July 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product not subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 18 September 2025